REMARKS

I. INTRODUCTION

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 52 is being added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1, 15, 19, 24, 28-39, 41-47 and 49-52 are pending in this application.

II. THE OFFICE ACTION

The Examiner has rejected claims 1, 15, 19, 24, 28-39, 41-47 and 49-51 under 35 U.S.C. §103 as allegedly unpatentable over Levy in view of Richter. Applicants respectfully traverse.

Levy discloses a group of hydro-monobenzoporphyrins "green porphyrins" (Gp) having absorption maxima in the range of 670-780 nanometers which are useful in treating disorders or conditions which are subject to hematoporphyrin derivative (HPD) treatment in the presence of light. The working examples of Levy are exclusively directed to benzoporphyrin derivatives. Levy used the benzoporphyrin derivatives against in vivo and in vitro tumor cells, to eliminate viral contaminants in a blood sample (Example 13), to treat atherosclerotic plaques (Example 14), and to treat papilloma-caused warts (Examples 16 and 17). All of the working examples relate to cells made abnormal by cancer or intracellular infective agents. The working examples only are related to cancer or intracellular infective agents. That is, none of the working examples are related to intracellular infective agents, let alone fungal infections or onchomycosis.

In the over 7,300 word specification of Levy, fungal infections are only mentioned twice, in two consecutive paragraphs, from c. 18, l. 67 to c. 19, l. 33. Applicants contend that this scant mention of putative fungal treatment, without more, is not an enabling disclosure nor a disclosure that provides a reasonable expectation of success with HPD for photodynamic therapy. Likewise, there is no enablement or reasonable expectation of success with using an even more dissimilar photodynamic therapy, one which uses a precursor of protoporphyrin IX.

Levy is directed to administering agents which are themselves photoactive agents, which are activated by a wavelength of light in the range of 670-780 nm. The present application is directed to administration of a substance which is not itself a photoactive agent, e.g., a precursor of protoporphyrin IX. In fact, the elected agent for administration is ALA and is not itself a photosensitizer.

Levy is silent on precursors of protoporphyrin IX, prodrugs of protoporphyrin IX or 5-aminolevulinic acid.

Richter is directed to photodynamic therapy using a photoactive agent for treating tumors. The working examples of Richter teach the injection of benzoporphyrin derivative – monoacid ring (BPD-MA) into mouse tumors and then the mice were exposed to light within 30 minutes of injection. (See e.g. c. 9, Table 1). The alleged inventive concept of Richter is that lower doses and earlier light exposure can be achieved with BPD-MA than previously thought. (See c. 7, ll. 45-50.).

Richter at column 5, line 62 to column 6, line 5, does mention eight classes of preferred photosensitizing agents. One of the eight classes is "prodrugs such as δ-aminolevulinic acid." More preferred, however, are benzoporphyrin derivates and porfimer sodium (a.k.a. dihematoporphyrin ether sodium), both of which are porphyrin ring structures, not porphyrin prodrugs. Most preferred of the benzoporhyrin derivatives are BPD-MA.

Richter teaches that photodynamic therapy was used for treating various forms of diseased tissue, where the actual cells of the diseased tissue are infected from within (See e.g. c. 5., ll. 50-55). The working examples of Richter are solid tumors, which are the body's own

cells that are growing in an unregulated manner. BPD was known to Richter to have a higher affinity for tumor cells, and hence be useful in photodynamic therapy.

Another type of unwanted cell that Richter mentions in passing is a cell infected with a virus. (See e.g. c. 2, ll. 12-15 or c. 4, ll. 23-25.) The beginning of the Stryer article provided by the examiner mentions that viruses are intracellular parasites, that are unable to generate metabolic energy or synthesize protein (and therefore must hijack these functions from normal cells, turning them into virally infected cells.) As a result of a virus manifesting itself in a cell, the cell turns into an abnormal cell that synthesizes viral proteins. Interestingly, Stryer also mentions that viruses can be a source of cancer because of the altered oncogenes that viruses harbor.

There is no teaching in Richter of treatment of extracellular parasites in a patient with PDT of any type, let alone a prodrug for PDT. Richter never mentions that any type of extracellular parasite, such as fungi, could be successfully treated with any type of PDT. At most, Richter demonstrates that BPD-MA, a fully formed porphyrin, can be injected into tumors and consequently irradiated. Richter only conjectures without providing evidence that such a treatment maybe useful with "virus-containing cells." Thus, Richter neither suggests nor provides a reasonable expectation of success that exogenous agents can be treated with PDT.

Richter cannot remedy the deficiencies of Levy. Both Levy and Richter provide guidance to photodynamic therapy using an agent which is photoactive. There is no teaching or suggestion in Levy or Richter to use an agent which is not itself a photosensitizer, such as ALA, for the treatment of onychomycosis or any other disease or skin lesion. Rather, Richter mentions in passing that a prodrug such as ALA could be used but provides nothing more than supposition that a prodrug such as ALA could be used. Instead, Richter and Levy both teach, with numerous examples, a photoactive agent, such as the disclosed green porphyrins of Levy or the photosensitizing agents of Richter. In fact, Richter states that his invention uses "photosensitizing agents." (col. 3, lines 34-43, "while this invention provides for the use of any photosensitizing agent, preferably the agent is selected from . . ."). While Richter states "a prodrug such as of δ aminolevulinic acid," there is no teaching of success in

Richter's methods for using ALA and at most there is a suggestion amounting to "obvious to try." Moreover, the obvious to try would only apply to the disease states disclosed by Richter, which do not include fungal infections and certainly do not provide any teaching for treating onychomycosis. In this regard, the examiner is using an improper "obvious to try" standard, arguing that it would have been obvious to a person of ordinary skill in the art familiar with the teachings of Richter and Levy to try to treat fungal infection by ALA exposing the infected site to light. However, "'obvious to try' has long been held to not constitute obviousness." *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210 (Fed. Cir. 1995). Therefore, the combined teachings of Levy and Richter cannot render the presently claimed invention obvious.

Reconsideration and withdrawal of the rejection are respectfully requested in light of the above remarks.

III. CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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